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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,821	12/21/2000	Daniel C. Carter	P06652US01/BAS	6567
881 7590 10/16/2008 STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314				
EXAMINER				
LIU, SAMUEL W				
ART UNIT		PAPER NUMBER		
1656				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/740,821

Applicant(s)

CARTER, DANIEL C.

Examiner

SAMUEL W. LIU

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50 and 52-58 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50 and 52-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C2)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DTAILED ACTION

Status of claims

Claims 50 and 52-58 are pending.

The amendment filed 7/11/08 which adds claim 58, and amends claims 50, 52, 54-55 and 57 has been entered. Claims 1-49 and 5 have been cancelled by the applicant's amendment filed 10/31/07. Claim 58 is drawn into the examined invention. Claims 50 and 52-58 are examined in this Office action.

The applicant's request filed 7/11/08 for extension of time of three months has been entered.

Withdrawal of claim rejections

[1] The rejection under 35 USC 102(b) of claims 50 and 52-56 by Mausner, J. is withdrawn in light of the amendment of claims 50 and 54 with regard to the claim limitation the cleansing agent ...about 5 to 55% by weight of the liquid soap" (the limitation is new matter, see below). It is of note that this 102(b) rejection may be reiterated upon removal of the new matter.

[2] The rejection under 35 USC 102(b) of claims 50, 52, 54-56 by Beaulieu A. is withdrawn in light of the amendment of claims 50 and 54 with regard to the claim limitation the cleansing agent ...about 5 to 55% by weight of the liquid soap" (the limitation is new matter, see below). It is of note that this 102(b) rejection may be reiterated upon removal of the new matter.

New-Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 50 and 52-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement; this is a new matter rejection. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitations (i) "the cleansing agent ...about 5 to 55% by weight of the liquid soap" (claims 50, 54 and 57); and (ii) "the cleansing agent is about 0.3:1 to 2.4:1 by weight..." (claim 58)", which as amended into the claims on 7/11/08, is not supported in the specification as originally filed. Applicant can either cancel the new matter or point out specification support for the phrase in the specification as originally filed.

Maintained- Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 50 and 52-56 remain, and claim 58 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 50 and 54 recites "... and a cleansing agent, vehicle, carrier or excipient", and claim 58 recites "... the cleansing agent, vehicle, carrier or excipient"; the recitations are unclear whether or not vehicle, carrier or excipient is the cleansing agent. Similarly, claim 58 recitation "... the cleansing agent, vehicle, carrier or excipient" Claims 52-53 which depend from claims

50, and claims 55-56 which depend from claim 54 are also rejected because these claims do not cure the defect of claim 50.

* Examiner note: the applicant's "Remarks" filed 7/11/08 contain no response to the rejection under 35 USC 112, second paragraph set forth in the Office action mailed 1/11/08.

New-Claim Rejections - 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

• Claim 58 is rejected under 35 U.S.C. 102(b) as anticipated by Mausner, J. (US Pat. No. 5254331).

In patent claim 6 and Table 1, Mausner teaches a skin cream composition comprising human serum albumin (item *i*), and steareth-21 which is a surfactant and cleansing agent for cosmetic use (see "*Discussion of art*" [3]) and which accounts for ~ 1.3%-1.7% of the composition. Water or glycogen set forth in Table 1 and claim 6 is considered to be equivalent to instant "carrier". Since "soap" is a cleansing agent (see "*Discussion of art*" [2] set forth in the Office action mailed 1/11/06). Also, Mausner teaches that the protein complex comprises about 28% serum protein (col. 7, line 3), wherein the protein complex comprises ~6.9% of the skin cream composition; thus, the human serum albumin is 1.9% (calculation: $28\% \times 6.9\% = 1.9\%$) of

said composition. The ratio of the albumin (1.9 %) to cleansing agent (1.3% -1.7%, see above) is about 1.1 to 1.5 by weight. Thus, Mausner teaches claim 58.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragton, can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

/Samuel W Liu, Ph.D./

Examiner, Art Unit 1656

October 14, 2008

/Karen Cochrane Carlson, Ph.D./

Primary Examiner, Art Unit 1656

New-Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 54-55 are rejected under 35 U.S.C. 102 (a) as anticipated by or, in the alternative as obvious under 35 U.S.C. 103(a) over Nielsen et al. (*Biochem. Biophys. Acta* (2000, June) 1479, 321-331). Although the invention is not identically disclosed or described as set forth in 35 U.S.C. 102, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a designer having ordinary skill in the art to which said

In “*Materials and methods*” section, Nielsen et al. teach a composition comprising a bovine serum albumin (BSA), and a detergent, i.e., sodium laurate, wherein said detergent is dissolved in liquid buffer comprising 20 mM Tris, 100 mM NaCl, pH7.0. This composition is considered to be a cleansing composition because the sodium laurate is a cleansing agent derived from coconut oil from which soap can be made (see “*Discussion of Art*”). At the left column, page 322, Nielsen et al. teach that like human serum albumin (HSA), bovine serum albumin (BSA) has the same property, e.g., having high affinity of binding the surfactant. Because in Nielsen et al. paper, the bovine albumin is substituted for HSA for testing its affinity for surfactants), BSA and HSA are exchangeable herein. Therefore, the Nielsen et al. teachings are applied to claim 54.

At page 322, right column, the last two lines, Nielsen et al. teach that 100 μ M of BSA which is equivalent to 6.7 mg/ml (BSA molecular weight: 67,000 daltons) is dissolved in the solution comprising 4 mM of cleansing agent, i.e., \sim 1.15 mg/ml sodium laurate (in light of sodium laurate molecular weight: 288 daltons), which is applied to instant claim 55.

Please note that “cleansing agent” has been given itself patentable weight in claim 54, and that the current claim language as written is broadly drawn to encompassing any type of

detergent cleansing agent. Also, note that the preambles “*for skin or hair*” after “*cleansing composition*” (claims 50 and 54), and “*hypoallergenic cleaning*” before “*composition*” (claims 50 and 54) are considered to have little patentable weight. This is because structural feature is an inherent property of a molecule or composition; the above-stated functional preambles “*for skin or hair*” and “*hypoallergenic cleansing*” will not alter property/components of the claimed composition. It is of note that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. See MPEP 2112.01.

Applicant's response to the rejection under USC 35 102(a)

On pages 4-5, the response filed 1/16/07 submits that Nielsen et al. do not teach recombinant HSA and is a theoretical paper relating of surfactant binding to BSA, and argues that Nielsen does not teach that sodium laurate is a cleansing agent but rather teach test for SDS and the similar surfactant (page 5). Also, the response argues that Nielsen et al. teach nothing regarding the hypoallergenic composition for human treatment. Thus, the response infers that the Nielsen et al. reference teaches away from the claimed composition, and thus requests withdrawn the rejection (if applied to the new claims).

The applicant's arguments are found unpersuasive because of the reasons below. Nielsen et al. is a 102/103 prior art herein (see above) wherein BSA and HSA are structurally and functionally exchangeable. The sodium laurate is a typical cleaning agent which has been discussed in the section “*Discussion of art*”, wherein acting as a cleaning agent is inherent

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property of the sodium laurate. Nielsen et al. clearly teach that sodium laurate is SDS like detergent (see Figure 1). As discussed above, functional preamble languages, e.g., “*hypoallergenic*” and “*for hair and skin*” have little patentable weight to the claimed composition. Thus, Nielsen et al. teach the disclosed composition comprising the albumin and the cleansing agent thereof, and therefore, the rejection is proper.